K081538

RTI | BIOLOGICS™

ADVANCING SCIENCE, SAFETY & INNOVATION

JUN 19 2008

Attachment 4: 510(K) Summary

May 30, 2008

Submitted by: Lisa Simpson
RTI Biologics, Inc.
11621 Research Circle
Alachua, FL 32615
Phone: 386-418-8888 x4326
Fax: 386-418-1627

Proprietary Names: TUTOMESH®

Common Name: Surgical Mesh

Product Code: 79 FTL, Orthopedics Panel

Code Section: 21 CFR 878.3300

Substantial Equivalence:
The TUTOMESH® device is substantially equivalent to predicate devices in materials, design, function, intended use and fundamental scientific technology.

Description:
TUTOMESH® is a bovine pericardium surgical mesh processed with the Tutoplast® solvent dehydration process followed by gamma irradiation. The TUTOMESH® device consists of collagenous connective tissue with three-dimensional intertwined fibers. Therefore, it has a multidirectional mechanical strength and can be fixed regardless of the direction of the graft. Collagenous connective tissue with multidirectional fibers retains the mechanical strength and elasticity of the native tissue, while providing the basic structure to support replacement by new endogenous tissue.

Intended Use:
These products are indicated for use in general and plastic surgery applications. These products are intended for repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias).

Summary of Technological Characteristics:
TUTOMESH® has materials, design and function equivalent to predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2008

RTI Biologics, Inc.
% Ms. Lisa Simpson
Director of Regulatory Affairs
11621 Research Circle
Alachua, Florida 32615

Re: K081538
Trade/Device Name: TUTOMESH®
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTM, MFX
Dated: May 30, 2008
Received: June 2, 2008

Dear Ms. Simpson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2: Indications for Use

510(k) Number (if known): K081538

Device Names: TUTOMESH®

Indications for Use:

These products are indicated for use in general and plastic surgery applications. These products are intended for repair of pericardial structures and for use as a prosthesis for the surgical repair of soft tissue deficiencies which include: gastric banding, muscle flap reinforcement, rectal and vaginal prolapse, reconstruction of the pelvic floor, and hernias (including diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, and umbilical hernias).

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081538